UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

IN RE NUVARING® PRODUCTS LIABILITY LITIGATION	)	**4:08-md-01964 RWS**
	)	
	)	**ALL CASES**
	)	
	)	**Honorable Rodney W. Sippel**
	)	
	)	***DOCUMENT ELECTRONICALLY FILED***

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE TESTIMONY OF SHELLEY ANN TISCHKAU, PH.D.

Melissa A. Geist
REED SMITH LLP
Princeton Forrestal Village
136 Main Street, Suite 250
Princeton, NJ 08540
(609) 987-0050

Thomas J. Yoo
REED SMITH LLP
355 S. Grand Avenue
Suite 2900
Los Angeles, CA 90071
(213) 457-8000

Dan H. Ball
Stephen G. Strauss
BRYAN CAVE LLP
One Metropolitan Square
211 North Broadway, Suite 3600
St. Louis, Missouri 63102-2750
(314) 259-2000

Attorneys for Organon USA Inc., Organon Pharmaceuticals USA Inc. LLC (f/k/a Organon Pharmaceuticals USA Inc.) Organon International Inc. and Merck & Co., Inc. (f/k/a Schering-Plough Corporation)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page**

Federal Rules

Other Authorities

INTRODUCTION

Throughout her entire academic career, including the eight years she spent in the Departments of Animal Science and Veterinary Bioscience at the University of Illinois, plaintiffs' purported pharmacology expert, Shelley Ann Tischkau, Ph.D., has had no experience with human research. Her research has been exclusively on animals and has centered on circadian rhythms—the concept that physical and other changes occur in an organism over a 24-hour cycle in response to light and darkness in their environment—including their applications to pet care. The opinions she has offered in this litigation concern two topics far afield from this professional focus: (1) thrombosis—the formation of blood clots in humans; and (2) pharmacokinetics—the study of what the human body does to drugs (e.g., absorption, distribution, metabolism, and excretion). Dr. Tischkau has absolutely no expertise in either area.

Dr. Tischkau's main opinion involves the risk of blood clots to users of third-generation hormonal contraceptives, including NuvaRing®, compared to the risk for users of other combined hormonal contraceptives, but she has never diagnosed or treated a blood clot, has never done any type of research on blood clots, and, by her own admission, is "not a clotting expert." Her deposition testimony confirmed that she lacks a fundamental understanding of the clotting process and related concepts. And although she has never been involved in a clinical trial on any pharmaceutical product and has not reviewed the product label or a single piece of clinical trial data for any hormonal contraceptive other than NuvaRing®, Dr. Tischkau has offered opinions based on her assessment of the pharmacokinetic data in NuvaRing®'s product label and its clinical trials. Dr. Tischkau's testimony should be stricken because she is incompetent to assist the trier of fact in deciding the issues in this case.

Lacking credentials in the fields in which she has rendered opinions and having failed to do the research necessary to inform her understanding, Dr. Tischkau resorted to plagiarism in preparing her report. Early in her deposition, she represented that every word in her report was her own, and that the reference list in the report's Appendix A was intended to be "complete and comprehensive." But her subsequent testimony revealed that she had cut and pasted passages from a variety of sources left off of her reference list—including the general information website, About.com, and a ***veterinary*** manual. Dr. Tischkau did not use quotation marks or indicate in any way that the language or ideas were not her own. In her deposition, she acknowledged that she had also "lifted from" other undisclosed sources.

While Dr. Tischkau's plagiarism is the most striking example of the unreliability of her methodology, it is hardly the only one. She had no support for a number of her statements and opinions, and was at a loss to explain others. In particular, Dr. Tischkau could not articulate any scientific methodology for concluding that NuvaRing® presents an increased risk of thrombosis. Indeed, she has not reviewed pharmacokinetic data for any other hormonal contraceptive, and had no information or expertise about what a "normal" or "safe" level would be for any of the measurements she discusses in her report. Moreover, it is apparent from her testimony that she did not bother to read the studies that she claims support her overarching opinion that third-generation contraceptives present a greater risk for venous thromboembolism ("VTE"), the type of blood clot at issue in this litigation. Accordingly, Dr. Tischkau's opinions should be excluded for the additional reason that they are not supported by "good grounds and appropriate validation."

STATEMENT OF FACTS

A. Dr. Tischkau's Background.

Dr. Tischkau holds a Ph.D. in Physiology and is an Assistant Professor in the Department of Pharmacology at the Southern Illinois University ("SIU") School of Medicine (Exh. A, Deposition of Shelley Ann Tischkau, Ph.D. ("Tischkau Depo."), Exh. B; Curriculum Vitae of Shelley Ann Tischkau, PhD ("Tischkau CV") at 1-2, appended to Exh. C, Expert Report of Shelley Ann Tischkau, Ph.D. ("Tischkau Report").) Dr. Tischkau's report, submitted on August 1, 2011, states that "the vaginal contraceptive, NuvaRing, carries a higher risk for the development of serious adverse side effects, including VTE, than other, more well-established contraceptives" (Tischkau Report at 21.) She bases that conclusion largely on her analysis of a pharmacokinetic clinical trial on NuvaRing®. (*Id.* at 21-22.)[1] In less technical terms, Dr. Tischkau has opined that NuvaRing® carries a higher risk for the formation of blood clots than do other hormonal contraceptives, and is basing that opinion on her evaluation of blood tests performed on users of NuvaRing® during a clinical trial.

Dr. Tischkau is an animal scientist, not a medical doctor or a clinical researcher, and has never treated or diagnosed humans or performed studies involving human tissue (Tischkau Report at 3; Tischkau Depo. 65-68, 86-87, 90-91.) All three of her graduate theses were on topics of animal physiology – involving the chicken ovary, the rat brain, and "gut segments of the Pacific Hagfish" (Tischkau CV at 1; Tischkau Depo. 73-75.) From 1999 until she went to SIU in 2007, Dr. Tischkau was first a Visiting Assistant Professor in the Department of Animal Sciences and then an Assistant Professor in the Department of Veterinary Biosciences at the University of Illinois at Urbana-Champaign (Tischkau CV at 1-2; Tischkau Depo. 75.) She has

[1] "Pharmacokinetics" is "the study of the bodily absorption, distribution, metabolism, and excretion of drugs." Merriam-Webster's Collegiate Dictionary, 10th ed. (1993).

published 10 papers on rats, nine studies on mice, and six on chickens. (Tischkau Depo. 75-76; Tischkau CV.) Dr. Tischkau has never "published any papers with data collected from human beings." (Tischkau Depo. 76.)

The Department of Pharmacology at SIU describes Dr. Tischkau as "exploring molecular and neurological bases that underlie whole animal physiological processes, neurotoxicity, circadian rhythms, and environmental toxicology" (Tischkau Depo. 77-78; Exh. 3 to Tischkau Depo, attached as Exh. D.), and she agreed that the description accurately summarizes her current research (Tischkau Depo. 79). Dr. Tischkau also confirmed, more specifically, that the largest focus in her research and her current area of expertise are "[c]ircadian rhythms as they relate to endocrine function." (*Id.* 159-60, 167).[2]

B. Dr. Tischkau's Qualifications Relating to Thrombosis and Pharmacokinetics.

By her own admission, Dr. Tischkau is "not a clotting expert." (Tischkau Depo. 135.) She has no expertise in thrombosis or in VTEs, or in hematology in general. (*Id.* 92, 112, 297.) None of her research or publications has been on thrombosis (*id.* 77), and she has "no idea what's accepted or not accepted" as a mechanism in thrombosis (*id.* 192). She does not know what a pulmonary embolism is (*id.* 113); nor does she know how VTEs are diagnosed or treated (*id.* 133). Dr. Tischkau knows only "generally" how clots form (*id.* 133), and knows nothing about the body's anticoagulation system (*id.* 134-35).

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[2] Dr. Tischkau described circadian rhythms as "24-hour oscillations in biological functions . . . in the expression of various hormones, various . . . behaviors, all sorts of things" (Tischkau Depo. 160). "Circadian Rhythms Influence Pet Behavior," an article on the website of the University of Illinois's College of Veterinary Medicine, provides her recommendations to pet owners for "alter[ing] their animals' exposure to light or chang[ing] the timing of other influencing factors" to adjust their behavior. The article states, for instance, that "[a]n animal's response to light can be overridden and its circadian rhythms altered if the timing of essential activities is altered. For example, Dr. Tischkau makes sure her kittens have playtime in the early evening so that they are tired out by late night, and she feeds them at night so they don't bother her at 5 a.m. for food" (Tischkau Depo. 197-99; http://vetmed.illinois.edu/petcolumns/petcols_article_page.php?PETCOLID=285&URL=0.) Dr. Tischkau confirmed that her advice in the article is an example "of how the clock influences behavior," and was based on her expertise in circadian rhythms (Tischkau Depo. 199).

Despite opining that NuvaRing® carries a higher risk of VTE than other contraceptives (Tischkau Report at 21), Dr. Tischkau stated that she "is not qualified to answer" when asked to list the risk factors for VTE (Tischkau Depo. 130). Similarly, she did not know the incidence rate of VTEs among non-users of hormonal contraceptives (Tischkau Depo. 114, 117, 121); users of third-generation hormonal contraceptives (*id.* 127); users of second-generation oral contraceptives (*id.* 125-26); or women who are pregnant or post-partum (*id.* 128-29). Nor did Dr. Tischkau have an opinion on what an acceptable rate of VTE is for women using hormonal contraceptives (*id.* 128).

Dr. Tischkau is not an M.D. or a clinical pharmacologist. (Tischkau Report at 3; Tischkau Depo. 66-67, 86-87, 90-91.) She has not published any papers or done research on any medications, including hormonal contraceptives. (Tischkau Depo. 76-77, 90-91.) Nor has she ever done a study or published a paper on human pharmacokinetics. (*Id.* 88.) Dr. Tischkau has never been involved in a pharmaceutical clinical trial, and before she was retained as an expert in this case, she had never reviewed a clinical trial on or the product label for any hormonal contraceptive. (*Id.* 92-93, 95.) The NuvaRing® product label is the only hormonal contraceptive label she has ever reviewed. (*Id.* 95.) Dr. Tischkau has never had any communication with any medical doctor about the label for any hormonal contraceptive, including NuvaRing®. (*Id.* 147.)

C. Dr. Tischkau's Representations Regarding Her Report and Appendix A.

Appended to Dr. Tischkau's 22-page report are her CV and several appendices, including Appendix A, titled "Materials Considered by Dr. Shelley Tischkau." Appendix A, which comprises five pages, states, "In addition to the materials specifically referenced in my report, the other materials I have considered are" and lists those materials by category: "Literature,"

"Other Documents," and "Deposition Testimony." (*See* Appendix A to Tischkau Report.) On November 2, 2011, the evening before her deposition was taken, Dr. Tischkau submitted to defendants' counsel a Supplemental Appendix A (attached as Exh. E), which added a number of entries, typed in bold and underscored, that were not on the original Appendix A (Tischkau Depo. 11-12.)

Dr. Tischkau explained that in going over her report with plaintiffs' counsel the day before her deposition, "we realized . . . there were a couple of papers published more recently that I considered and then there were a couple of other minor things that needed to be included that hadn't been included originally." (*Id.* 12-13.) According to Dr. Tischkau, the original "Appendix A includes things that I considered in writing my report," and she testified that she had "tried to be complete and comprehensive" in preparing it. (*Id.* 17.) She added that, after supplementation, "[a]s far as I know … it's complete at this time." (*Id.* 26.) Appendix A "contains the materials that [she] considered" (*id.* 31; 32-33); if materials are not referenced there, she "didn't think that they were important to include" (*id.* 27).

In addition to these repeated representations that Appendix A was intended to be a "complete" list of the materials she relied on for her report, Dr. Tischkau also testified, early in her deposition testimony, that "every word" in her expert report was her own, based on her own work and expertise. (*Id.* 24.) Similarly, Dr. Tischkau's report asserts that "[t]he opinions expressed in this report were derived using the same analytical processes that I routinely use in my profession as a University Professor and Research Scientist, including my education and experience in reproductive endocrinology and pharmacology." (Tischkau Report at 2.) She elaborated that she prepared her report using "the same process that I would use in analyzing scientific data," and agreed that she would be proud both to publish her report in a peer-reviewed

journal and to share it with her colleagues and students at the SIU School of Medicine. (Tischkau Depo. 61.) "I wouldn't write anything that I . . . wouldn't stake my scientific reputation on." (*Id.* 61.)

D. Dr. Tischkau's Plagiarism.

Despite these assurances, Dr. Tischkau ultimately acknowledged not only that large sections of her report were lifted verbatim (or nearly so) from various materials, but that those other materials were not disclosed in either the original or Supplemental Appendix A. When initially confronted with a charge that she had plagiarized the works of others, Dr. Tischkau responded, "I ***don't recall*** plagiarizing." (Tischkau Depo. 201 (emphasis added).) Asked if a sentence in her report, "Estrogens promote the synthesis of several hepatic proteins and have a well-established prothrombotic effect" reflected her own words, Dr. Tischkau – who had earlier acknowledged that she is "not a clotting expert" (*id.* 135) – replied that she "wrote that sentence after reading the literature" (*id.* 201). Defense counsel then showed Dr. Tischkau an article, "*History of Oral Contraception*," by Marc Dhont, that was published in The European Journal of Contraception and Reproductive Health Care (Dec. 2010) (the "Dhont article").[3] The Dhont article contains the same sentence with one slight alteration – Dhont employed the British English spelling variation, "oestrogen" (Tischkau Depo. 201, 202). Dr. Tischkau ultimately acknowledged having read the article. (Tischkau Depo. 202.)

Further questioning and comparison of the documents demonstrated that the Dhont article's "contributions" to Dr. Tischkau's report were far more extensive than one sentence. In all, Dr. Tischkau "borrowed," without attribution and with varying degrees of alteration, 13

[3] A .pdf of the article is available at http://informahealthcare.com/doi/abs/10.3109/13625187.2010.513071

sentences from five different paragraphs in Dhont (*see* Tischkau Depo. 202-213).[4] A chart comparing passages from Dr. Tischkau's report with their source in the Dhont article is attached as Exhibit F. Together, these sentences comprise the better part of four paragraphs of the Tischkau report. (Tischkau Report at 5-6.) Confronted with her wholesale cutting-and-pasting from the Dhont article, Dr. Tischkau conceded that the article was not on her reference list in Appendix A, and that "[i]n some cases I used the exact sentences" without quoting the source. (Tischkau Depo. 204, 214.)

Equally noteworthy is what Dr. Tischkau did not borrow from Dhont. In particular, her report included Dhont's discussion of papers published in *The Lancet* in 1995-96, reporting that the relative risk of VTE associated with third-generation pills "was twice that of second-generation pills" (Tischkau Report at 5-6). Yet, she omitted the sentences immediately following, which explained that "[s]ubsequent analyses have mitigated but not totally disproved these epidemiological findings but the debate on the precise effects of different hormonal contraceptives on the haemostatic system is still going on." (Dhont at S15.)

The Dhont article is not the only unattributed source for Dr. Tischkau's report. She was next asked about "Understanding the Types of Progestin in Birth Control," by Dawn Stacey, M.Ed, LMHC, an article found on the website, About.com.[5] Exhibit G, comparing passages from Dr. Tischkau's report with a portion of the About.com article, shows that the two contain identical phrases and sentences as well as other similarities. Dr. Tischkau declared, "I did not intentionally plagiarize anybody." (Tischkau Depo. 225.)

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[4] One difference is that while the Dhont article refers to doses of various estrogens and progestins in micrograms, using the International System of Units symbol, "µg," Dr. Tischkau's report incorrectly refers to doses of those hormones in milligrams, using the abbreviation, "mg." (Tischkau Report at 5.) A milligram is 1,000 times greater than a microgram. When text containing the "µg" symbol is cut from a pdf file and pasted to a Word document, Word, which does not recognize the "µg" symbol, replaces it with "mg."

[5] *See* http://contraception.about.com/od/thepill/p/Progestins.htm.

When defense counsel asked Dr. Tischkau whether what she had done is considered plagiarism in academic circles and questioned her about her university's plagiarism policy, Dr. Tischkau refused to answer, stating variously, "I don't think I should answer that," "I should have included it. That's all I'm going to say," and "I have already answered it. I'm not going to say anything other than what I have already said." (Tischkau Depo. 226-227; 229-230.)

Subsequent examination disclosed that Dr. Tischkau had appropriated text from at least two other sources without attribution. Three paragraphs in her report are largely identical to passages from "Vaginal Drug Delivery," by Vidya Iyer, N. Bendguide, S.S. Poddar, from expresspharmaonline.com.[6] A chart comparing passages from Dr. Tischkau's report with their source in the expresspharmaonline.com article is attached as Exhibit H. Dr. Tischkau acknowledged that she used the article to write her report (Tischkau Depo. 239-240; 242, 244); that she "didn't cite it" (*id.* 242); and that her report contained some identical language without attribution (*id.* 244; *see also id.* 245). Dr. Tischkau was as selective in lifting passages from the expresspharmaonline.com article as she was in taking text from the Dhont paper. She left out portions favorable to the defendants' position, including statements that "[u]npredictable GI [gastrointestinal] absorption consequent upon oral administration can be further complicated by vomiting, drug-drug interaction, or decreased intestinal absorption"; that one drug, "when administered vaginally has been shown to be more effective, having fewer side effects than when administered orally," and that "[m]any of the conventional oral medications are now being switched to vaginal route." (Tischkau Depo. 253-54.)

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6 *See* http://www.expresspharmaonline.com/20080715/research02.shtml.

The fourth unattributed piece that Dr. Tischkau "borrowed" from –"Drug Absorption," *The Merck Veterinary Manual*[7] – is an unlikely resource for an expert report in a case dealing with *human* contraceptives. The similarities between Dr. Tischkau's list of 11 factors governing gastrointestinal drug absorption and a very similar list of 13 factors in the Manual speak for themselves. A chart comparing the list from Dr. Tischkau's report with the list in *The Merck Veterinary Manual* is attached as Exhibit I. Of note, one of the two factors in the *Manual*'s list that do not appear in Dr. Tischkau's report is "morphologic and functional differences of the GI tract among the various animal species."

Asked "when you testified under oath that every word in your report was your own, you weren't being truthful, were you," Dr. Tischkau responded: "I think it's perfectly honest to use – to use other sentences – to use other people's sentences when you – in – in writing things, you can do that." (Tischkau Depo. 266-267.)

E. Dr. Tischkau's Opinions.

The Conclusion section of Dr. Tischkau's report sets forth her opinion that "NuvaRing carries a higher risk for the development of serious adverse side effects, including VTE, than other, more well-established contraceptives." (Tischkau Report at 21.) The section sets forth four "reasons for this conclusion," which, broadly summarized, are as follows: (1) the etononogestrel ("ENG") in NuvaRing® is a third-generation progestin which, according to Dr. Tischkau, "carries a higher risk for the occurrence of thromboembolic events" (*id.* at 21); (2) "[t]he variability in the delivered dose of EE [ethinyl estradiol, the estrogen in CHCs] demonstrated in Clinical Trial 34218 suggests that further pharmacokinetic testing regarding EE profiles and its effects should have been conducted" (*id.*); (3) "[t]he 'burst' effect observed in

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[7] *See* http://www.merckvetmanual.com/mvm/htm/bc/190103.htm.

serum EE levels" in some subjects in Trial 34218 "is a cause for concern" because "[e]levated levels of estrogen are known to increase risk of VTE," and the longer "Tmax" – the time for a hormone to reach maximal concentration in the blood serum – for ENG compared to the Tmax for EE "leaves a significant time frame where estrogen may be unopposed by progestin, which could contribute to the development of VTE in certain women" (*id.* at 21-22); and (4) "[d]ue to the variability of the PK parameters among the Clinical Trial subjects, NuvaRing is more pro-thrombotic in certain women than an oral dose of the same progestin and estrogen" (*id.* at 22).

F. Dr. Tischkau's "Methodology."

Dr. Tischkau's deposition brought to light a number of aspects of her purported methodology in forming her opinions. For example, in support of her opinion that NuvaRing®, as a third-generation product, presents a higher risk for VTE, her report states that "[i]ndependent studies indicate that . . . 3rd generation progestins, in combination with an estrogen, carry a 2-fold elevated risk for the occurrence of thromboembolic events." (Tischkau Report at 21.) When asked about these "independent studies," she responded that there were "approximately 16 epidemiology studies . . . and so 3 of those showed no change and about 13 of those showed an increased risk." (Tischkau Depo. 282-83.) She obtained those numbers from a review paper by Vandenbroucke, but acknowledged that the 16 studies are not on her reference list and that while she had "seen some of the 16 studies," she had not read them. (Tischkau Depo. 283-290.) In the same vein, Dr. Tischkau did not know the reasons why, in her opinion, second-generation progestins are safer. (*Id.* 390-91.)

Besides these "independent studies," the only other study Dr. Tischkau cites in support of her opinion that NuvaRing® carries a higher risk for VTE is a "cross-over study" indicating that "NuvaRing use carried . . . higher SHBG [sex hormone binding globulin] levels," compared to a

second-generation oral contraceptive. (Tischkau Report at 21.) Dr. Tischkau further states that the study "confirmed the use of SHBG as a marker for thrombotic risk of all hormonal contraceptives." (*Id.*) But in her deposition, she acknowledged that she has no expertise with regard to SHBG as it relates to thrombosis, does not know what a safe or unsafe level of SHBG is, and has "no expertise in measuring SHBG." (Tischkau Depo. 307-09.)

Dr. Tischkau's testimony also established that she has no scientific support for other statements in her report. For instance, her report sets forth "the fact" that "delivery of hormones vaginally causes increased variability." (Tischkau Report at 21.) She admitted, however, that there is, "[o]f course," variability in the gastrointestinal ("GI") environment for drug delivery (Tischkau Depo. 358-59), and that she has no "data to show that the vagina is more stable or less stable" an environment for drug administration than is the GI system (*id.* 360). Dr. Tischkau also conceded that even though she stated opinions in her report about vaginal pH levels and their effect on vaginal administration of drugs (Tischkau Report at 11), she "[doesn't] have a scientific opinion" about the vaginal pH levels in NuvaRing® users (Tischkau Depo. 444-45).

Further, Dr. Tischkau's report refers to the "striking" and "significant" variability in serum EE concentrations among the subjects in NuvaRing®'s clinical trial (Tischkau Report at 12, 13), and states that "[d]ue to the variability" in the data from that trial, "NuvaRing is more pro-thrombotic in certain women than an oral dose of the same progestin and estrogen" (*id.* at 22). But she did not review the label or clinical trial data for any other hormonal contraceptive because she "was not asked to look at any other clinical data." (Tischkau Depo. 93, 95, 423.) Similarly, Dr. Tischkau opined that the NuvaRing® label was "misleading" because it indicated that the data were from an N of 16 when one data point was from an N of 5, and stated that "a reasonable physician may have cause to question it if they saw an N of 5." (*Id.* 421-22.)

However, she has never prescribed a hormonal contraceptive, as she is not a medical doctor, and has never spoken with any prescribing medical doctor about a hormonal contraceptive. She had no evidence that anyone would not have prescribed NuvaRing® if the label showed an N of 5 for a given measurement, and in fact did not know what the N is for the pharmacokinetic data for any other hormonal contraceptive. (*Id.* 422-23.)

Moreover, based on her observations of the EE levels in the pharmacokinetic data, Dr. Tischkau's report draws the following conclusions: (1) the "'burst' effect observed in serum EE levels is a cause for concern [because] [e]levated levels of estrogen are known to increase risk of VTE" (Tischkau Report at 21); and (2) the longer Tmax for etongestrel ("ENG") compared to the Tmax for EE "leaves a significant time frame where estrogen may be unopposed by progestin, which could contribute to the development of VTE in certain women" (*id.* at 22). But she admitted that no safe or unsafe level of estrogen exposure "has ever been established" (Tischkau Depo. 343-44; *see also id.* 375); that she has no opinion on "what levels of progestin are required to counterbalance the effects of estrogen" (*id.* 379); and that she doesn't "think it's been established what levels of [unopposed estrogen] need to be present" to "put people . . . at risk for thrombosis" (*id.* 356).

GOVERNING LAW

Federal Rule of Evidence 702, which governs the admission of expert testimony, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert

> has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. As the Supreme Court made clear in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, Rule 702 compels courts to act as "gatekeepers" concerning the admissibility of expert scientific and technical evidence to make certain that unreliable testimony does not reach the jury. 509 U.S. 579, 597 (1993); *see also Polski v. Quigley Corp.*, 538 F.3d 836, 838-39 (8th Cir. 2008). "[T]he district court's gatekeeping role separates expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 988-89 (8th Cir. 2001); *see also Daubert*, 509 U.S. at 589-90. Even a "supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based on some recognized scientific method." *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004), quoting *Clark v. Takata Corp.*, 192 F.3d 750, 759 n. 5 (7th Cir. 1999). Thus, expert testimony is admissible only when three requirements are satisfied:

> First, the expert must be qualified to testify competently regarding the matter he or she intends to address. Second, the methodology used must be reliable as determined by a Daubert inquiry. Third, the testimony must assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue.

Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1335 (11th Cir. 2010); *see also Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (listing the "three prerequisites" for the admission of proposed expert testimony under Rule 702).

The Eighth Circuit has described the trial court's gatekeeping obligation with regard to a proposed expert's qualifications as follows:

> A witness can be qualified as an expert by 'knowledge, skill, experience, training or education,' Fed. R. Evid. 702, and it is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in the case. … Once initial expert

> qualifications and usefulness to the jury are established, however, a district court must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert's expertise . . . . *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001) (citation omitted).

To meet the reliability requirement, the "methodology underlying the testimony [must be] scientifically valid." *Daubert*, 509 U.S. at 592-93. An expert's methodology is "the materials and methods" he or she relies on "to form [his or her] opinions." *Kilpatrick*, 613 F.3d at 1336. "An expert opinion 'must be supported by appropriate validation – i.e., "good grounds," based on what is known.'" *Glastetter*, 252 F.3d at 988 (quoting *Daubert*, 509 U.S. at 590). Testimony that is speculative should not be admitted. *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 448 (8th Cir. 2010).

To determine whether a specific methodology is reliable, the Supreme Court has suggested a non-exhaustive list of relevant factors to consider, including: (1) whether the expert's testimony can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community. *Daubert*, 509 U.S. at 593-94. Among the other issues the trial court should consider is "whether the expertise was developed for litigation." *Polski*, 538 F.3d at 839 (quoting *Lauzon*, 270 F.3d at 686-88).

In *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151-52 (1999), the Court clarified that the *Daubert* list of factors "was meant to be helpful, not definitive," and emphasized that the trial court "must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." Justice Breyer explained that the emphasis on reliability is meant to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at

152. In other words, there cannot be one standard for science in the laboratory and another for science in the courtroom.

Plaintiffs, as the proponent of Dr. Tischkau's testimony, bear the burden of establishing by a preponderance of the evidence that her testimony meets all of the Rule 702 requirements. *Polski*, 538 F.3d at 841.

As set forth below, plaintiffs cannot satisfy this burden for two important reasons. ***First***, Dr. Tischkau lacks the training and qualifications necessary to offer the opinions included in her report – and cannot cure this deficiency by simply "reading up" for trial. ***Second***, her opinions are inherently unreliable because they are in large part plagiarized from other sources and, in any event, are not the product of a legitimate scientific methodology.

I. DR. TISCHKAU'S TESTIMONY SHOULD BE EXCLUDED BECAUSE SHE IS NOT QUALIFIED TO TESTIFY ABOUT THE RISKS OF VTE IN HUMANS.

The centerpiece of Dr. Tischkau's report is her opinion that women who use NuvaRing® are at a greater risk for developing blood clots than users of contraceptives containing a second-generation progestin. (Tischkau Report at 21.) But Dr. Tischkau – an animal scientist whose work focuses on circadian rhythm – is manifestly unqualified to offer opinions on this subject. Nor could she cure her lack of qualifications by reviewing literature solely for the purpose of testifying in this litigation. Indeed, despite her claim to have undertaken a literature review, her deposition testimony makes clear that she continues to have a "fundamental lack of understanding" of the relevant scientific issues in this case.

First, Dr. Tischkau is not "qualified as an expert by knowledge, skill, experience, training or education," because she has no expertise in pharmacokinetics or thrombosis. *See Arnold v. Amada N. Am., Inc.*, No. 4:07CV198 RWS, 2008 U.S. Dist. LEXIS 60434, at *6 (E.D. Mo. Aug.

8, 2008) (one "purpose of this court's inquiry regarding expert testimony is to make certain that the proffered expert is . . . qualified").

As a threshold matter, Dr. Tischkau's own admissions that she is not an expert on thrombosis, VTEs, or hematology (Tischkau Depo. 92, 112, 297), are fatal to the admissibility of her testimony. Court after court has concluded that an expert witness is unqualified to render opinions on an area in which he or she has explicitly disclaimed expertise. *In re Trasylol Prods. Liab. Litig.*, No.1:08-MD-01928, 2010 U.S. Dist. LEXIS 140204, at *159 (S.D. Fla. May 17, 2010) (excluding expert testimony regarding the effects of prescription drug Trasylol; the witness's "lack of expertise with Trasylol is clear" where she "admitted that she is not an expert" on the drug); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 n.40 (S.D.N.Y. 2004) (expert was not qualified to offer opinions involving profit motives where he acknowledged that he was not an expert on the subject of corporate intent; "[i]n the face of [his] admissions . . . the testimony [the witness] proposes to give in this case is based on a series of inferences with no basis in fact or scientific method") (emphasis omitted); *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-md-1760, 2009 U.S. Dist. LEXIS 71599, at *16-17 (M.D. Tenn. Aug. 13, 2009) (expert witness was not qualified to offer opinions regarding osteonecrosis of the jaw where he "clearly admitted that he is not an expert" on the subject; therefore "[t]he Court cannot and has not considered the testimony . . . for purposes of summary judgment").

In *In re Vioxx Products Liability Litigation,* for example, the court denied the plaintiff's motion to reconsider its prior exclusion of causation testimony offered by a cardiologist, where the doctor had himself testified that he lacked expertise to form such an opinion. MDL No. 1657, 2005 U.S. Dist. LEXIS 36518, at *2 (E.D. La. Dec. 3, 2005). In adhering to its prior ruling, the court noted that the physician admitted that he was "[n]ot an expert, per se" on the

subject of Cox-2 drugs, and concluded that "[i]f [the witness] is not willing to consider himself an expert on the effect of Cox-2 inhibitors, it would seem quite peculiar for this Court to qualify him as one." *Id.* at *8.

The same reasoning applies here. Dr. Tischkau's main opinion pertains to the risk of blood clots to NuvaRing® users as compared to users of other combined hormonal contraceptives. Yet she has unequivocally disclaimed any expertise in thrombosis, VTEs, or hematology. During her deposition, Dr. Tischkau stated that she is "not a clotting expert," (Tischkau Depo. 135, 293, 298), and, when asked to identify the risk factors for VTE, responded that she was "not qualified to answer" (*id.* 130). "If [Dr. Tischkau] is not willing to consider [herself] an expert on [thrombosis, VTE's or hematology], it would seem quite peculiar for this Court to qualify [her] as one." *In re Vioxx*, 2005 U.S. Dist. LEXIS 36518, at *8. For this reason alone, the Court should exclude her testimony in its entirety.

Even absent this concession, however, it is obvious that Dr. Tischkau is unqualified to render opinions on either human pharmacokinetics or thrombosis. It is well-settled that "[a] party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue." *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2001 U.S. Dist. LEXIS 1174, at *22 (E.D. Pa. Feb. 1, 2001) (cardiologists "highly qualified within their particular disciplines" were not qualified to render opinions regarding regulatory standards, obesity, and the efficacy of the disputed drug where they did not treat obesity and one witness had not prescribed a diet drug). Accordingly, courts have repeatedly excluded expert testimony where – as here – the proffered testimony exceeds "the reasonable confines of [a witness's] subject area." *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) (affirming district court's finding that an orthopedic

surgeon specializing in oncology was not qualified to render opinions regarding intramedullary nailing); *Grant v. Bristol-Myers Squibb*, 97 F. Supp. 2d 986, 991 (D. Ariz. 2000) (chemist holding a Ph.D. in physical chemistry was not qualified to testify that breast implants were allegedly defective because he was "not a medical doctor and has not supported his theories with testing."); *Wade-Greaux v. Whitehall Lab., Inc.*, 874 F. Supp. 1441, 1465 (D. V.I. 1994) (clinical pharmacologist did "not have any special training or experience that qualifies him to testify . . . regarding birth defects or their causes"); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1287, 1292-93 (N.D. Okla. 2000) (family practitioner specializing in emergency medicine was not qualified to opine as to causation in product-liability action involving allegedly defective spinal fixation device; a "blanket qualification for all physicians to testify as to anything medically-related would contravene the Court's gate-keeping responsibilities").

More specifically, courts routinely exclude expert testimony involving humans where the expert's experience is limited to plants or animals. *See, e.g.*, *In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 809-810 (M.D. Pa. 1996) (excluding testimony of biologist who specialized in studying effects of radiation on plants; although the witness was "well credentialed in his own field," he had never studied human medicine" or "diagnosed or treated people with acute radiation illness," and was not qualified to testify in fields including medicine, epidemiology, and immunology); *see also Wade-Greaux*, 874 F. Supp. at 1462-63, 1477 ("highly regarded bench scientist" specializing in cellular biology was not qualified to render general causation opinions in product-liability action involving alleged birth defects caused by nasal decongestant; the witness's "work pertain[ed] to controlled *in vitro* experiments using chick embryo cells," and he was "not a physician and [did] not work with humans or human data . . . and testified that he finds it confusing"); *Abdishi v. Phillip Morris*, No. 98 C 1310, 1999 U.S. Dist. LEXIS 14903, at

*22-23 (N.D. Ill. Sept. 7, 1999) (expert witness was not qualified to render opinions regarding the nature of plaintiff's illness where "he ha[d] never treated a patient and [was] not a medical doctor," and his knowledge regarding infections and blood cell counts involved animals only).

That is precisely the case here: Dr. Tischkau has no business opining on ***human*** pharmacokinetics because her knowledge, research, and expertise is confined to ***animal science***. (*See* Tischkau Depo. 67, 75-76.) Just as in *In re TMI*, Dr. Tischkau has no experience researching or treating humans. She is not a medical doctor or clinical researcher, and has never treated or diagnosed any human or done any research on human tissue. (*See id.* 67, 75-76.)[8] She has never conducted a human pharmacokinetic study (*id.* 88, 90), has never published a paper on human pharmacokinetics (or, more broadly, on any medications or human data) (*id.* 90, 91), and has never been involved in a clinical trial on any pharmaceutical product (*id.* 92). Thus, although she may be "well credentialed in [her] own field" of animal physiology, she is not qualified to render any opinions pertaining to human pharmacokinetics. *In re TMI Litig. Cases Consol. II*, 911 F. Supp. at 809.

Not only does Dr. Tischkau not have ***any*** expertise with respect to humans, but she has no experience in the pharmacokinetics of combined hormonal contraceptives ("CHCs") or in thrombosis, VTEs, or hematology – whether in humans or animals.

In re Meridia Products Liability Litigation, 328 F. Supp. 2d 791, 805 (N.D. Ohio 2004), is instructive on this point. There, the court precluded a pharmacologist from providing expert opinions regarding cardiology and obesity issues, finding that – while the expert was well qualified in his own field – he did not have the expertise to testify in others. *Id.* The court

[8] Asked whether she had ever consulted with a medical doctor for purposes of treating a patient, Dr. Tischkau testified that she had been "called by various doctors over the years." (Tischkau Depo. 68-69.) But when pressed for names, she could identify only one, Dr. Kathy Bottum, with whom she lives and owns property. (*Id.* 69-71.)

explained that "[a]s to the scope of [the witness's] testimony, a district court must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert's expertise[.]" *Id.* at 804, quoting *Wheeling Pittsburgh*, 254 F.3d at 715. Accordingly, the court found that although the witness was "knowledgeable about cardiovascular pharmacology," his "background, while impressive, does not qualify [him] to give expert testimony best suited for a cardiologist," including testimony that a particular drug "causes adverse cardiovascular effects" and that "a particular level of injury will result from a certain level of blood pressure increase." *Id.* at 802, 805. For similar reasons, the court found that the witness was "not qualified to testify as an obesity expert." *Id.* Specifically, the court found that the expert's "involvement with obesity is fairly limited," and the mere fact that the expert had "attended symposia on weight loss and lectured regarding obesity" was not enough to establish that he was "specially qualified to testify" on the effects of weight loss on health. *Id.* at 805.

Just as in *In re Meridia*, Dr. Tischkau's proposed testimony far "exceed[s] the scope of [] [her] expertise." *Id.* at 804. Indeed, Dr. Tischkau is not even remotely knowledgeable about the subjects on which she seeks to opine. Dr. Tischkau has no expertise in the pharmacokinetics of CHCs. Further, nothing in Dr. Tischkau's 22-page CV indicates any expertise in pharmacokinetic analysis; she cannot prescribe medications, nor is she a clinical pharmacologist. (Tischkau Report at 3; Tischkau Depo. 66-67, 86-87, 90-91.) In addition, while Dr. Tischkau claims expertise in hormonal contraceptives (Tischkau Depo. 93), she has never done research involving those drugs or published any papers on them (*id.* 76-77), and the NuvaRing® product label is the only hormonal contraceptive label she has ever reviewed (*id.* 95). Indeed, the extent of her expertise on this subject is an annual two-hour lecture she gives on hormonal contraceptives to second-year students at the SIU School of Medicine. (*Id.* 315-16.) As the

court noted in *In re Meridia*, this is not sufficient to qualify her as an expert on hormonal contraceptives. 328 F. Supp. 2d at 805.

Dr. Tischkau is equally unqualified to render any opinions pertaining to thrombosis or VTEs, or in hematology. Dr. Tischkau herself admits that she has never researched or published any papers on thrombosis. (*See* Tischkau Depo. 77.) And while she claims that she knows "generally" how clots form, she concedes that she knows nothing about the human body's anticoagulation system. (*See id.* 134-35.) Indeed, she is "not a clotting expert." (*Id.* 135.)

In short, Dr. Tischkau may hold a Ph.D., but she has no expertise "on the specific issues in the case." *See Wheeling Pittsburgh*, 254 F.3d at 715. Accordingly, her testimony must be excluded.

Second, to the extent Dr. Tischkau sought to remedy her lack of qualifications in the subjects of human pharmacokinetics and thrombosis simply by reviewing literature in connection with this litigation, that effort cannot overcome her lack of expertise. "Courts are suspicious of purported expertise premised solely or primarily on a literature review." *Smith v. Rasmussen*, 57 F. Supp. 2d 736, 766-67 (N.D. Iowa 1999), *rev'd on other grounds by* 249 F.3d 755 (8th Cir. 2001). Indeed, "[s]uch a literature review [] is an insufficient basis or methodology on which to render a reliable expert opinion." 57 F. Supp. 2d at 767.

In *Harvey v. Rines*, No. 98-85-P-DMC, 1999 U.S. Dist. LEXIS 22386 (D. Me. Jan. 19, 1999), for example, the defendants designated a board-certified internist and liver specialist to testify about the metabolic processes that affected the body's response to the disputed drug, arguing that the witness had "extensive knowledge" on the subject and "ha[d] performed research and written extensive publications in the field of toxicology." *Id.* at *18-19. Plaintiffs moved to exclude his testimony, arguing that the witness had "no direct experience or scientific

knowledge that qualif[ied] him to opine about this case, [and] that his opinions were formulated specifically for this litigation[.]" *Id.* at *18. The court agreed, noting that it had "several problems" with the proffered testimony; "most important[ly], [the witness's] testimony, taken as a whole, clearly reveals that his proffered opinions are based primarily upon a review of certain medical literature undertaken specifically for this case." *Id.* at *24 (citation omitted). Accordingly, the court was "left with the impression that [the witness's] testimony [was] more unscientific speculation offered by a genuine scientist than it is genuinely scientific[.]" *Id.* (internal quotation marks and citation omitted).

Numerous decisions are in accord. *See, e.g., Burton v. Danek Med., Inc.*, No. 95-5565, 1999 U.S. Dist. LEXIS 2619, at *11-12 (E.D. Pa. Mar. 1, 1999) (board-certified neurologist was not qualified to offer opinions in the area of spinal fusion surgery where "[t]he only medical literature he reviewed was that provided by Plaintiffs' counsel, and his curriculum vitae discloses no independent research regarding spinal fusion surgery or any related area of medicine."); *Wade-Greaux*, 874 F. Supp. at 1476 (physicians who had not engaged in any studies relating to the issues upon which they offered expert opinions, but merely reviewed "selected literature . . . for purposes of testifying in litigation" were not qualified to offer opinion testimony); *Mancuso v. Consolidated Edison Co.*, 967 F. Supp. 1437, 1443 (S.D.N.Y. 1997) (where expert witness reviewed a "large number of documents" sent by plaintiffs' attorney in advance of preparing his amended report, the court could not "help but conclude that [the witness] was not in fact an expert in PCBs when he was hired by plaintiffs, but that he subsequently attempted, with dubious success, to qualify himself as such by a selected review of the relevant literature").

Precisely the same logic applies here. Dr. Tischkau's main opinion in this case – i.e., that NuvaRing® carries a higher risk for the formation of blood clots than do other hormonal

contraceptives – is based largely on her analysis of pharmacokinetic clinical trial data on NuvaRing®, which she reviewed solely for the purpose of testifying in this lawsuit. Before she was retained as an expert in this case, she had never reviewed ***any clinical trials for any hormonal contraceptives***, which is not surprising given her actual area of expertise. As one court aptly noted, a witness's claimed expertise is belied by a "need to rely upon the attorney for the plaintiff to supply [her] with the relevant scientific literature[.]" *Mancuso*, 967 F. Supp. at 1443.

Dr. Tischkau's effort to educate herself as an expert was all the more inadequate because her literature review was woefully incomplete. *Diaz v. Johnson Matthey, Inc.*, 893 F. Supp. 358, 372-73 (D.N.J. 1995) (expert witness was not qualified to testify where, in preparation for litigation, he had "only casually studied the literature" on plaintiff's illness; "certainly ha[d] not studied any papers that contradict[ed] his opinion" and had "at best a limited familiarity with the small amount of literature in the field"). With respect to CHCs, Dr. Tischkau has not reviewed clinical trials for any hormonal contraceptive other than NuvaRing®. (*See* Tischkau Depo. 93.) Nor has she reviewed data regarding any other controlled release product. (*See id.* 350-53.) Indeed, NuvaRing® is also the only hormonal contraceptive for which Dr. Tischkau has reviewed the product label (*id.* 95), and she has never talked to any medical doctor about NuvaRing®'s label or the label for any other hormonal contraceptive (*id.* 147). It is telling that, even after being retained as an expert and evaluating the data from Clinical Trial 34218, Dr. Tischkau did not bother to look at the clinical trials or product label for any other hormonal contraceptive: "I wasn't asked to look at any other clinical data." (*Id.* 423.)

In short, Dr. Tischkau has, "at best a limited familiarity with the small amount of literature in the field," and otherwise "totally lacks experience" in the relevant scientific areas.

Diaz, 893 F. Supp. at 373. For these reasons too, she is clearly unqualified and her testimony must be excluded.

Finally, even if it were ever proper to develop expertise by reviewing limited literature, Dr. Tischkau's effort to do so plainly failed because she does not grasp basic concepts concerning human pharmacokinetics and thrombosis. Dr. Tischkau's "fundamental lack of understanding" with respect to the scientific concepts underlying her opinions makes her all the more unqualified to testify. *In re Vioxx*, 2005 U.S. Dist. LEXIS 36518, at *8.

There is broad judicial recognition that a witness's inability to answer basic scientific questions during a deposition is a telltale sign that the witness is unqualified to render opinions under Rule 702. In *In re Vioxx*, 2005 U.S. Dist. LEXIS 36518, at *9-10, for example, the court denied a motion to reconsider its prior exclusion of an expert witness's testimony that Vioxx had caused the decedent's death. Plaintiff argued that the witness's "skill, training and education" as a cardiologist was "sufficient to qualify him to testify as an expert regarding the proclivity of Vioxx to produce clot formations." *Id.* at *7-8. But the court rejected this position, concluding that "[a]n examination of [the witness's] deposition testimony leads to the opposite conclusion." *Id.* at *8. In explaining its ruling, the court noted that "[i]n his deposition, [the witness] displayed a fundamental lack of understanding of the relevant scientific literature . . . [and] was unable to explain or recount the results and implications of the numerous tests and studies conducted with Vioxx and other Cox-2 inhibitors." *Id.* "Simply put," the court stated, "[the expert's] reliance on the relevant scientific literature was completely underminded [sic] by his inability to firmly understand this literature." *Id.* Accordingly, the court deemed the witness unqualified to testify on the effects of Vioxx or any other similar drugs. *Id.* at *8-9; *see also Mancuso*, 967 F. Supp. at 1443-44 (granting motion to exclude expert testimony where the

proffered witness was "unable to answer critical questions regarding PCBs;" in particular, it was "troubling" that the witness's deposition testimony "revealed he had no clear idea what levels of PCB contamination would be dangerous to humans"); *Arnold*, 2008 U.S. Dist. LEXIS 60434, at *10 (witness was not qualified to offer opinions regarding press brake machines where his deposition testimony "continuously demonstrated his lack of experience and expertise"; the expert "kn[ew] almost nothing about the press brake machine in this case, including the model number and basic design information . . . and cannot name a single manufacturer of press brakes"); *Arista Records LLC v. Lime Group LLC*, No. 06 CV 5936 (KMW), 2011 U.S. Dist. LEXIS 47416, at *17-18 (S.D.N.Y. Apr. 29, 2011) (expert in technology and computer science was not qualified to offer opinions about statistics or surveying issues where "he was unable to provide specifics about the particular statistical methodologies he has used" and was "unwilling (if not unable) to answer basic questions about statistical principles at his deposition"); *Diaz*, 893 F. Supp. at 372 (excluding expert testimony where the witness "was unable to testify as to the content of the single article he had read prior to writing his report without constantly referring to the article"; "[n]or could he remember much about the material he had gathered a few weeks prior to testifying").

Here too, Dr. Tischkau "displayed a fundamental lack of understanding of the relevant scientific" issues pertaining to hematology, thrombosis or VTEs. *In re Vioxx*, 2005 U.S. Dist. LEXIS 36518, at *8. She does not know what a pulmonary embolism is (Tischkau Depo. 113), cannot explain how the clotting process works, other than in broad terms (*id.* 133), and knows nothing about the body's anticoagulation system (*id.* 134-35). She has "no idea what's accepted or not accepted" as a mechanism in thrombosis. (*Id.* 192.) She was also unable to provide basic information about VTEs. She does not know how VTEs are diagnosed or treated. (*Id.* 133.)

Nor does she know the incidence rate of VTEs among women who do not use hormonal contraceptives (*id.* 114, 117, 121), among users of second-generation oral contraceptives (*id.* 125-26), among users of third-generation contraceptives (*id.* 127), or among pregnant or post-partum women (*id.* 128-29).[9] Dr. Tischkau also has no opinion on what an acceptable rate of VTE is for women using hormonal contraceptives. (*Id.* 128.)

Similarly, despite claiming expertise in hormonal contraceptives (*id.* 93), Dr. Tischkau struggled to answer basic questions on the subject. Most notably, she asked to refer to her notes to name some first-generation hormonal contraceptives (*id.* 100-101); she offered only two examples when asked to name any hormonal contraceptives other than NuvaRing® (*id.* 104-05); and she misstated that Ortho Evra® is a pill (*id.* 105), when it is actually a skin patch, as her own report indicates. (Tischkau Report at 19, 21 (discussing "the Otho [sic] Evra Patch").)

Dr. Tischkau's lack of expertise was also apparent when she was questioned in her deposition about certain statements in her report. She was asked, for example, about APC (Activated Protein C) resistance and SHBG, both of which are mentioned several times in her report in connection with the risk of VTE. (Tischkau Report at 19, 21.) However, she did not know what APC resistance is or how it is measured. (Tischkau Depo. 299-301, 303.) Similarly, Dr. Tischkau conceded that she has no expertise in measuring SHBG or how SHBG relates to thrombosis. (*Id.* 308-09.) She does not know what a safe or unsafe level of SHBG is. (*Id.* 308.) Thus, even though her report discusses both APC resistance and SHBG levels as they

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[9] Besides showing that she has no expertise, Dr. Tischkau's lack of knowledge of these incidence rates is significant because "[a] reliable methodology should take into account the background risk . . . [which] is the risk . . . members of the general public have of suffering the disease or injury that plaintiff alleges ***without*** exposure to the drug or chemical in question"). *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005).

purportedly relate to NuvaRing® use and the risk of thrombosis, Dr. Tischkau lacks a fundamental understanding of either.[10]

In sum, Dr. Tischkau's deposition testimony "continuously demonstrated [her] lack of experience and expertise" pertaining to pharmacokinetics or thrombosis. *See Arnold*, 2008 U.S. Dist. LEXIS 60434, at *10. For this reason, too, her testimony must be excluded.

* * *

Dr. Tischkau is a classic example of a witness who developed her purported expertise "for litigation." *See Polski*, 538 F.3d at 839. Nothing in her CV indicates any education, training, research, or other expertise that qualifies her to render opinions on the relative risks of VTE from use of NuvaRing® compared to other CHCs. Nor does her CV demonstrate any expertise in pharmacokinetic analysis, let alone expertise that would allow her to draw from such data any conclusions regarding the risk for thrombosis. Further, Dr. Tischkau explicitly disclaimed any expertise in thrombosis, VTEs, or hematology. (Tischkau Depo. 92, 112, 297.) Moreover, as evidenced by her deposition testimony, Dr. Tischkau's cursory, incomplete literature review – undertaken solely for purposes of testifying in this litigation – did not compensate for her utter lack of expertise in thrombosis or pharmacokinetics. For all of these reasons, the Court should exercise its gatekeeping authority to exclude Dr. Tischkau's testimony.

II. DR. TISCHKAU'S TESTIMONY MUST BE EXCLUDED BECAUSE HER OPINIONS ARE LARGELY THE PRODUCT OF PLAGIARISM AND OTHER UNRELIABLE METHODS.

Not only is Dr. Tischkau utterly unqualified to opine in this litigation, but her supposed "methodology" falls far short of the reliability standard set forth by *Daubert* and its progeny.

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[10] Dr. Tischkau could not identify any literature that accepts SHBG or APCr as a marker for the risk of thrombosis (Tischkau Depo. 311-12, 313-14), and did not know whether any medical organization recognizes SHBG as such a marker (*id.* 312). In fact, neither the FDA nor any medical organization recognizes either SHBG or APCr as a valid marker for the risk of thrombosis.

This is so for two reasons. Most significantly, Dr. Tischkau's opinions are largely the product of plagiarism. And even if she had not cut-and-pasted much of her analysis, her opinions would still be inadmissible because Dr. Tischkau did not do the legwork to obtain the data and knowledge necessary to support them.

A. Dr. Tischkau's Plagiarism Is A Tell-Tale Sign Of Unreliable Testimony.

Notwithstanding Dr. Tischkau's repeated protests that she "did not intentionally plagiarize" the work of others, her report is fraught with plagiarism. This inescapable fact renders her testimony utterly unreliable.

Where credibility bears on a witness's methodology in forming opinions, "a district court would necessarily have to address and resolve the credibility issue . . . to arrive at a conclusion regarding the reliability of the methodology at issue." *Elcock v. Kmart Corp.*, 233 F.3d 734, 750-51 n.8 (3d Cir. 2000). As such, numerous courts have weighed issues of credibility in determining whether an expert's testimony is sufficiently reliable to be admitted at trial. *See, e.g.*, *id.* at 750-51 ("under certain circumstances, a district court, in order to discharge its fact-finding responsibility under Rule 104(a), may need to evaluate an expert's general credibility as part of the Rule 702 reliability inquiry"); *Miller v. Pfizer, Inc.*, 356 F.3d 1326, 1335 (10th Cir. 2004) ("[t]he court did not exceed the scope of the *Daubert* inquiry by, for example, considering Dr. Healy's credibility or weighing the evidence" in excluding the expert testimony); *Cayenta Canada, Inc. v. Orange Cnty., Fla. Bd. Of Cnty. Comm'rs*, No. 6:01-cv-1232-Orl-22KRS, 2002 U.S. Dist. LEXIS 28257, at *21 (M.D. Fla. Nov. 20, 2002) ("[I]t is appropriate to consider a proposed expert witness's credibility in the reliability calculus when the credibility evidence relates significantly to methodology."); *see also In re UNISYS Sav. Plan Litig.*, 173 F.3d 145,

156 (3d Cir. 1999) ("Because [the witness] had testified untruthfully at *voir dire*, his testimony could well have been held unreliable.").

In *Elcock*, for example, the U.S. Court of Appeals for the Third Circuit considered the defendant's challenge to the district court's admission at trial of the testimony of a psychologist on the topic of vocational rehabilitation. 233 F.3d at 751. While it held that the expert's previous embezzlement and conversion of federal property did not weigh on the reliability of his methods, the court went to great lengths to make clear that it was ***not*** holding "that a district court [could] never consider an expert witness's credibility in assessing the reliability of that expert's methodology under Rule 702." *Id.* at 750-51 & n.8. Specifically, the court distinguished between issues of "general credibility," which should normally not be considered as part of a *Daubert* inquiry, and circumstances where – as here – "the credibility evidence at issue relates to the methodology before the court, and to the *Daubert* factors used to evaluate the reliability of that methodology." *Id.* The court elaborated as follows:

> [A] court should take . . . dishonesty or misconduct into account when the nexus between the acts and the expert's methodology is . . . direct – e.g., when the prior dishonest acts involve fraud committed in connection with the earlier phases of a research project that serves as the foundation for the expert's proffered opinion. *See* Edward J. Imwinkelreid, Trial Judges-Gatekeepers or Usurpers? Can the Trial Judge Critically Assess the Admissibility of Expert Testimony Without Invading the Jury's Province to Evaluate the Credibility and Weight of the Testimony, 84 Marq. L. Rev. 1, 39 (2000). Under this approach, for instance, the fact that an expert witness falsely reported his salary on an income tax return has little if any bearing on the reliability of a diagnostic test he frequently employs, but the fact that the expert lied about whether his methodology had been subjected to peer review, or intentionally understated the test's known rates of error, is a different matter entirely.

Id. at 751 n.8.

Since then, courts have applied *Elcock*'s guidelines to exclude expert testimony on credibility grounds. For instance, in *Cayenta Canada, Inc.*, a breach-of-contract case, the plaintiff moved to exclude the opinions of the defendant's expert witness, who testified that Cayenta "did not follow generally accepted, sound software engineering practices, processes and principles." 2002 U.S. Dist. LEXIS 28257, at *14. The court excluded the expert testimony under *Daubert* for a number of reasons, including obvious credibility issues that "directly relate[d] to [the witness's] methodology," thereby rendering the opinions unreliable. *Id.* at *24. On the day before the witness's deposition, he sent a disguised email to Cayenta's customer relations department asking for information about the company's Utility Manager System. *Id.* at *22. The court rejected the witness's contention that he sent the email out of sheer "curiosity" or as a "prank." *Id.* at *23. Rather, the court explained, "[i]t is obvious that [he] sent the message the day before his deposition in an effort to obtain information that would support or confirm his opinions concerning this case, thereby assisting him in preparing for the deposition." *Id.* The court further highlighted that "[i]t is equally obvious that [the witness] would have made use of any helpful information contained in a reply e-mail." *Id.* at *23-24. According to the court, "the very act of sending a disguised e-mail to Cayenta on the eve of his deposition detracts from [the witness's] credibility," and because "these credibility issues directly relate to [the witness's] methodology as an expert, they are relevant for *Daubert* purposes" and "lend[ ] further support to the Court's decision to exclude his testimony." *Id.* at 24; *see also United States v. Herrera*, 788 F. Supp. 2d 1026, 1034, 1035-36 (N.D. Cal. 2011) (outlining proposed expert's "tendency to mislead" and "to leave false impressions"; "Under *Daubert* and Rule 403, should a witness who persistently exaggerates, if not prevaricates, be tolerated merely because in those instances he is caught he will come clean? The Court thinks not").

This case calls for the same result. As in *Cayenta*, Dr. Tischkau's methodology cannot be deemed reliable because of the credibility issues that plague her expert report. As explained above, Dr. Tischkau represented – early in her deposition – that every word in her report was her own, and that the reference list in the report's Appendix A was intended to be "complete and comprehensive." But after she was confronted with the glaring similarities between her report and sources she did not include on Appendix A, Dr. Tischkau finally admitted to using those sources, including "exact sentences," without attribution. (Tischkau Depo. 214.)

For example, Dr. Tischkau's report copies nearly word-for-word the following sentence from an expresspharma article: "[a]n in vitro study reported release of prostaglandin E2 from vaginal preparations varies depending on the pH of the media." (*See* Exh. H.) Asked about that in vitro study, Dr. Tischkau responded, "I don't know who performed it . . . I have not read the study in detail . . . I have seen the study . . . I did not bring it with me." (Tischkau Depo. 251.) She did not know where the study was done or what it showed, and she did not cite to it. (*Id.* 251-52.) As one court explained in excluding expert testimony in similar circumstances, "the jury cannot determine whether the factual underpinnings of [the witness'] opinions are sound if [he] does not disclose all of the materials on which he relied in forming his opinions." *United States v. Vance*, No. 07 CR 0351, 2011 U.S. Dist. LEXIS 71787, at *12-13 (N.D. Ill. July 5, 2011) ("[T]he court cannot conclude that Dehus' methodology is reliable since Dehus did not adequately describe the bases and reasons for his opinions."); *see also Anderson v. A.J. Friedman Supply Co.*, 3 A.3d 545, 562 (N.J. Super. Ct. App. Div. 2010) ("[W]ithout plaintiffs knowing the exact documents, studies, or articles on which [the defendant's expert] had relied, they could not have examined the accuracy of his opinions."). In addition, absent such

information, defendants "cannot properly prepare for cross-examination or procure rebuttal evidence." *Vance*, 2011 U.S. Dist. LEXIS 71787, at *12-13.[11]

While Dr. Tischkau would have the Court believe that the failure to disclose these sources was simply an "inadvertent" oversight (Tischkau Depo. 204; 206-07; 208; 211; 213), such an assertion strains credulity.[12] After all, portions of some of these sources were copied virtually verbatim in Dr. Tischkau's report. In particular, as illustrated in the attached charts prepared by defendants, Dr. Tischkau essentially copied and pasted sections of the Dhont and *About.com* articles into her report. (*See* Exhibits F and G.) Thus, there can be no dispute that Dr. Tischkau's report was an exercise in plagiarism.[13]

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[11] Dr. Tischkau's failure to disclose the multiple sources from which she copied and pasted also runs afoul of Federal Rule of Civil Procedure 26(a)(2), which serves to "eliminate 'unfair surprise to the opposing party.'" *Werth v. Hill-Rom, Inc.*, No. 10-2235 (RHK/FLN), 2012 U.S. Dist. LEXIS 65259, at *22-23 (D. Minn. Apr. 18, 2012) (quoting *Sylla-Sawdon v. Uniroyal Goodrich Tire Co.*, 47 F.3d 277, 284 (8th Cir. 1995)). Pursuant to that rule, an expert report must include "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii); *accord Lohnes v. Level 3 Communs., Inc.*, 272 F.3d 49, 59 (1st Cir. 2001) ("[A] party retaining an expert must also submit to opposing counsel a detailed report covering, *inter alia*, . . . the ***sources*** of information underlying that opinion.") (emphasis added). Accordingly, Dr. Tischkau's "failure to disclose [her] reliance [on these other sources] . . . would alone justify excluding [her] opinion." *Werth*, 2012 U.S. Dist. LEXIS 6529, at *23; *see also Doblar v. Unverferth Mfg. Co.*, 185 F.R.D. 258, 262 (D.S.D. 1999) (granting defendant sanctions for plaintiff's expert's failure to fully disclose, pursuant to Fed. R. Civ. P 26(a)(2)(B), his prior engagements as an expert, and stating that his "failure to make an accurate and complete disclosure damages the integrity of the court system" and "violates the integrity of the process over which this Court presides").

[12] In any event, even if the Court were to accept such an assertion, the scale of the witness's inadvertence demonstrates a carelessness that should independently disqualify Dr. Tischkau from testifying. *See, e.g.*, *Solorio v. Asplundh Tree Expert Co.*, No. 02 Civ. 8035(RJS), 2009 U.S. Dist. LEXIS 23354, at *17 & n.9 (S.D.N.Y. Mar. 23, 2009) (in finding expert's testimony insufficiently reliable, court took into consideration "the various indicia of sloppiness and carelessness in [his] proposed expert opinion," including "copying the references from a previous expert report rather than conducting his own independent literature search," and "failing to review all of [those] references"); *see also Lemmermann v. Blue Cross Blue Shield*, 713 F. Supp. 2d 791, 809 n.21 (E.D. Wis. 2010) ("[T]he court finds the expert's approach sloppy and indicative of an unreliable method.").

[13] Notably, even if Dr. Tischkau had identified her sources, her lifted "opinions" would nevertheless be inadmissible because they "simply parrot[] the opinion[s] of" others – who are not available for cross-examination – and therefore do nothing to "assist the trier of fact." *Robinson v. Ford Motor Co.*, 967 F. Supp. 482, 487 n.2 (M.D. Ala. 1997); *Flagstone Dev., LLC v. Joyner*, No. CV-08-100-BLG-RFC, 2011 U.S. Dist. LEXIS 122643, at *8 (D. Mont. Oct. 24, 2011) ("[A]n expert's opinion must be excluded if that expert is merely 'parroting' some other person's opinion rather than formulating his own."); *Fowler v. United States*, No. 08-216, 2009 U.S. Dist. LEXIS 78805, at *26 n.59 (W.D. La. Sept. 1, 2009) (an expert cannot "simply parrot the work actually done by another expert, who is not offered for testimony and cross-examination"); *Fabrizi v. Rexall Sundown, Inc.*, No. 01-289, 2004 U.S. Dist. LEXIS 9859, at *30 (W.D. Pa. June 2, 2004) (rejecting expert testimony where the witness "in large part piggy-back[ed] on the opinions" of another physician); *Eberli v. Cirrus Design Corp.*, 615 F. Supp. 2d 1357, 1364

To make matters worse, Dr. Tischkau's cutting and pasting from these sources was not wholesale, but strategic. A careful examination of these sources reveals that she only appropriated passages she believed to be helpful to plaintiffs' case. For example, Dr. Tischkau cites Dhont's discussion of papers published in *The Lancet* in 1996-96 reporting that the relative risk of VTE associated with third-generation pills "was twice that of second-generation pills" (Tischkau Report at 5-6) and statements from an expresspharma.com article that discuss cyclic changes in the vaginal epithelium (Tischkau Depo. 242-44). But she was careful to omit sentences that support defendants' position, including: (1) the follow-up discussion in Dhont that "[s]ubsequent analyses have mitigated but not totally disproved these epidemiological findings but the debate on the precise effects of different hormonal contraceptives on the haemostatic system is still going on" (Dhont at S15); (2) the references in the expresspharma.com article to the potential complications related to GI absorption of drugs; and (3) the article's favorable references to vaginal administration of medications (Tischkau Depo. 253-54). *See* Exhs. F, H.

"[T]hese credibility issues ***directly*** relate to [Dr. Tischkau's] methodology as an expert." *Cayenta*, 2002 U.S. Dist. LEXIS 28257, at *24 (emphasis added). By preparing a report that contains phrases, sentences and passages lifted directly or with only slight alteration from the works of others – without quoting or even disclosing those materials on her reliance list – Dr. Tischkau's methodology can only be described as bootlegged. Indeed, these ***repeated*** instances of untruthfulness make the "nexus between [her dishonesty] and [ ] methodology" even "more direct" than in *Cayenta*. *Elcock*, 233 F.3d at 751 n.8. For this reason alone, Dr. Tischkau's testimony is unreliable and must be excluded.

(S.D. Fla. May 19, 2009) (expert witnesses "must make some findings and not merely regurgitate another expert's opinion").

B. Dr. Tischkau's Opinions Are Also Unreliable Because She Lacks Basic Knowledge About The Key Studies And Facts Necessary To Support Them.

Dr. Tischkau's testimony is also inadmissible because she lacks basic knowledge of the facts underlying her opinions. As set forth below, Dr. Tischkau's deposition testimony reveals that: (1) she has not read the studies that purportedly support her opinions concerning the risk of VTE allegedly posed to users of NuvaRing®; (2) she has no support for a number of critical statements in her report, expecting instead for the Court to simply take her at her word; and (3) she does not know at what level estrogen concentration becomes unsafe, undercutting her opinion that "elevated" levels of estrogen are known to increase the risk of VTE. For each of these reasons too, the Court should exclude her testimony from trial.

First, Dr. Tischkau's conclusion that "NuvaRing® carries a higher risk for the occurrence of thromboembolic events" must be excluded because it is based on studies she did not bother reading. Dr. Tischkau's report states that NuvaRing® carries an elevated risk of thromboembolic events and supports that conclusion by explaining that "[i]ndependent studies indicate that the use of 3rd generation progestins, in combination with an estrogen, carry a 2-fold elevated risk for the occurrence of thromboembolic events." (Tischkau Report at 21.) When asked about these "independent studies," Dr. Tischkau responded that there were "approximately 16 epidemiology studies," and while "3 of those showed no change," "about 13 . . . showed an increased risk." (Tischkau Depo. 282-83.) However, Dr. Tischkau was forced to admit that she obtained those numbers from a statement in a review paper by Vandenbroucke and that the 16 studies themselves were not on her reference list because she had seen only "some" of them. (*Id.* 283-85.) When she was pressed further, it became clear Dr. Tischkau only "look[ed] at" and "skimm[ed]" those "some." (*Id.* 287-90.)

Such a shoddy approach is unacceptable. As courts have made clear, expert testimony must be excluded where it is purportedly based on studies the expert did not properly analyze. *See, e.g.*, *Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 188-89 (E.D.N.Y. 2001), *aff'd*, 303 F.3d 256 (2d Cir. 2002); *Weiner v. Snapple Bev. Corp.*, No. 07 Civ. 8742 (DLC), 2010 U.S. Dist. LEXIS 79647, at *24-25 (S.D.N.Y. Aug. 3, 2010) (expert's testimony was unreliable because, "[i]nstead of reviewing the full text of the 'literature' that purportedly informed his testimony[,] . . . [the witness] oftentimes read only summaries and abstracts of articles, brochures for certain reports, and, in one case, the table of contents of a report"); *Abdishi v. Phillip Morris*, No. 98 C 1310, 1999 U.S. Dist. LEXIS 14903, at *16-17 (N.D. Ill. Sept. 7, 1999) (before offering an opinion, a scientist must "thoroughly research[ ] both the origins and the scientific method of the literature he is relying upon"). The reason is obvious: relying on studies without any "idea as to the[ir] origin, authorship, reliability or even authenticity" "hardly" evidences a "scientific or reliable approach." *Abdishi*, 1999 U.S. Dist. LEXIS 14903, at *16; *Smith*, 57 F. Supp. 2d at 766-67 ("This court is particularly suspicious here of the reliability of any opinions based on Dr. Kavalier's literature review, because . . . Dr. Kavalier based his belief that certain articles on gender identity disorder were reliable on a medical librarian's statement that articles on Medline were generally reliable.").

In *Amorgianos*, for example, the district court excluded the expert's testimony after learning that the expert had only read the abstracts of all the articles upon which he relied. *See* 137 F. Supp. 2d at 188-89. As the court explained, it had "grave doubts as to whether this constitutes a reliable methodology for researching medical evidence in support of an opinion on causation." *Id.* at 188. The court observed that an "abstract will, of necessity, fail to include details regarding the methodology and conclusions of the summarized study that may attenuate

or even destroy its relevance to the issue in question." *Id.* at 189. Thus, the expert's "disturbingly cursory research" mandated exclusion of his testimony. *Id.* at 188.

The same is true here. As set forth above, Dr. Tischkau "look[ed] at" or "skimm[ed]" only "some" of the sixteen articles upon which the central opinion she offers is allegedly based. Indeed, her "conclusion" about how these studies stacked up on whether an elevated thromboembolic risk exists with third-generation contraceptives like NuvaRing® was tallied by someone else. This blind reliance on a statement in one review paper means that, contrary to her representation, she did not take into account the methodology or statistical significance of the individual studies – which she acknowledged were the appropriate tools to test reliability – or even Vandenbroucke's assessment of them. (Tischkau Depo. 39-40.) Thus, like the experts in *Amorgianos* and *Abdishi*, she has no assurance that she did not overlook details that could undermine the reliability or relevance of the "independent studies" she cites. Indeed, if she had read the studies, she would know that only four of the sixteen reported a statistically significant difference in VTE risk between second- and third-generation hormonal contraceptives, that all four of those studies acknowledged the potential role of methodologic bias and confounding, and that important re-analyses of the data showing no difference in risk were ignored by the review paper. *See* "First-time use of newer oral contraceptives and the risk of venous thromboembolism," Suissa, et al., Contraception 1997;56:141-146; "Recurrent use of newer oral contraceptives and the risk of venous thromboembolism," Suissa, et al., Human Reproduction 2000(15);4:817-821.

Dr. Tischkau's failure to read and assess this literature on which she purportedly relies comes nowhere near the "meticulous and disciplined" methodology expected of expert

witnesses. *See Abdishi*, 1999 U.S. Dist. LEXIS 14903, at *17. For this reason too, her opinion that third-generation CHCs have an elevated VTE risk must be excluded.

Second, several of Dr. Tischkau's other opinions must be excluded because she is unable to offer ***any*** support for them at all.

It goes without saying that the "trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" *See* Fed. R. Evid. 702 advisory committee's note (2000); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). Indeed, the text of Rule 702 itself requires that expert testimony be "based upon sufficient facts or data." Fed. R. Evid. 702. Thus, where a court is "presented with only the experts' qualifications, their conclusions and their assurances of reliability," it must exclude the testimony because, under *Daubert*, "that's not enough." *Daubert*, 43 F.3d 1311, 1319 (9th Cir. 1995); *see Arnold*, 2008 U.S. Dist. LEXIS 60434, at *4; *Thomas v. City of Chattanooga*, 398 F.3d 426, 432 (6th Cir. 2005) (excluding expert's testimony where expert "provide[d] no rationale for his conclusions" and essentially "ask[ed] that we take [his] word for it"); *Placida Prof'l Ctr., LLC v. FDIC*, No. 8:09-cv-2221-T-30MAP, 2011 U.S. Dist. LEXIS 120502, at *19-20 (M.D. Fla. Oct. 18, 2011) (expert testimony excluded where expert "fail[ed] to explain the precise methodology used to derive his [ ] figure" and therefore failed to show that his testimony was "based upon any principles, and/or methods, let alone reliable ones" (emphasis omitted)).

In *Arnold*, for example, the plaintiff's fingers were allegedly crushed by a press brake machine designed and manufactured by the defendants. 2008 U.S. Dist. LEXIS 60434, at *1. The plaintiff's expert sought to testify that the machine was unreasonably dangerous because,

inter alia, it was not equipped with a hand-restraint system. *Id.* at *3. The court excluded this opinion, finding that the methodology used to reach it was not reliable. *Id.* at *12-14. As the court explained, there were too many "basic facts" central to the expert's opinion that the expert did not know. *Id.* For instance, the expert did not know "how the press brake at issue was set up," "the gap opening setting," "the closing speed," "the exact process that [the plaintiff] was engaged in," whether the plaintiff "would be able to reach the emergency stop buttons on the machine" if he was using a hand-restraint device, whether "other accidents occurred on [the] subject press brake or any other press brakes," or how "the design of [the defendant's] press brake [compared] to any other manufacturers' press brakes." *Id.* at 13-16. According to the court, these gaps in the expert's knowledge rendered his opinion inherently unreliable. *See id.*

Several of Dr. Tischkau's opinions suffer from precisely the same flaw. For example:

- Dr. Tischkau opined that "second-generation progestins are safer." But when asked to explain her basis for that opinion, she declared: "I don't think that I need to know the reason. They are safer." (Tischkau Depo. 390.)

- Dr. Tischkau also opines in her report that "delivery of hormones vaginally causes increased variability." (Tischkau Report at 21.) But she admitted in her deposition that she has no "data to show that the vagina is more stable or less stable" an environment for drug administration than is the gastrointestinal system. (Tischkau Depo. 360-61.) Dr. Tischkau also acknowledged that, despite stating opinions in her report about vaginal pH levels and their effect on the vaginal route of administration of drugs (Tischkau Report at 11), she "[doesn't] have a scientific opinion" on the issue (Tischkau Depo. 444-45.)

- Dr. Tischkau's report states that the "lack of androgenicity" in third-generation progestins "decrease[s] the ability of these compounds to counterbalance the effects of estrogens on production of clotting factors." (Tischkau Report at 21.) Again, however, she admits that she does not know how androgenicity affects clotting factors and that she cannot identify any data that support that opinion. (Tischkau Depo. 291-93.)

- Dr. Tischkau also makes observations throughout her report regarding the data reported in Trial 34218, noting the "striking" and "significant" variability in serum EE concentrations among the trial's subjects (Tischkau Report at 12, 13); the "unusual" "discrepancy" between the profiles of serum EE and serum ENG levels of the trial's subjects (*id.* at 13); and the "unreasonable" variability in the time (i.e.,

"Tmax") it took subjects to reach maximal serum concentration of EE (i.e., "Cmax") (*id.* at 17). But Dr. Tischkau did not review the label or clinical data for any other hormonal contraceptive because she "wasn't asked to look at any other clinical data." (Tischkau Depo. 423; *see also id.* 93, 345-46.) Thus, she has no framework for labeling the variability in the NuvaRing® data "significant," "striking," "unusual," or "unreasonable," let alone for her conclusion that "[d]ue to the variability of the PK parameters . . . , NuvaRing is more pro-thrombotic in certain women than an oral dose of the same progestin and estrogen." (Tischkau Report at 22.)[14]

- Dr. Tischkau further opined that the NuvaRing® label was misleading because one data point was from an N of 5, rather than an N of 16 as the label indicated.[15/] (Tischkau Depo. 421-22.) However, she has no knowledge of what the N was for the pharmacokinetic data on any other hormonal contraceptive (and has no evidence that an N of 5 would have caused anyone not to prescribe NuvaRing®). (*Id.* 422-23.)

The common theme among all of these examples is Dr. Tischkau's willingness to offer opinions and state them as fact without possessing any data to support them. In other words, Dr. Tischkau is defending her opinions by simply asking the Court to "take [her] word for it." *Thomas*, 398 F.3d at 432. The Court should not do so. Although Dr. Tischkau does not "think that [she] need[s] to know the reason[s]" behind her opinions (Tischkau Depo. 390), the caselaw is to the contrary. As the court made clear in *Arnold*, "expert methodology requires a more rigorous scientific analysis than the 'I say it's valid, therefore it must be valid' statement from an expert." 2008 WL U.S. Dist. LEXIS 60636, at *6. Because such a "rigorous scientific analysis" is not possible where, as here, the expert lacks "basic facts" about the subject at issue, *id*, Dr. Tischkau's opinion is inadmissible and must be excluded.

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[14] In her deposition, Dr. Tischkau stepped back from the statement in her report that "NuvaRing is more pro-thrombotic in certain women," saying, "I wouldn't use the word 'is.' I would use the word that it could be. It has the potential to be." (Tischkau Depo. 392-93.) That equivocation in itself underscores the unreliability of her opinions. *See McClain*, 401 F.3d at 1240 (expert's "trail of equivocations" led him from opining that ephedrine raises blood pressure to testifying that it "can" "aggravat[e]" blood pressure; by "dramatically dilut[ing] the value of [his] conclusions," the expert "impugn[ed] his methodology").

[15/] The data point at issue related to bioavailability percentages calculated in the study, which Dr. Tischkau did not dispute. Indeed, she did not "have any issues" with any of the pharmacokinetic values reported on the product label (Tischkau Depo. 457).

Third, and relatedly, Dr. Tischkau's opinion that "elevated" levels of estrogen are known to increase the risk of VTE must be excluded because she lacks knowledge of the most fundamental data point to reach that conclusion: what constitutes a safe or unsafe level for estrogen.

The Eighth Circuit has made clear that an expert who seeks to testify that exposure to a certain chemical can lead to a certain injury must account for "what amount of exposure to [the substance] causes, or involves an appreciable risk of causing, [that injury]." *Bland v. Verizon Wireless, L.L.C.*, 538 F.3d 893, 898 (8th Cir. 2008) (internal quotation marks and citation omitted); *Junk*, 628 F.3d at 448 (district court properly determined that would-be expert witness "had not used a 'scientifically valid' method to estimate that plaintiff's exposure [to chemical in insecticide] exceeded a safe level"). Numerous other courts are in accord, recognizing that "the link between an expert's opinion and the dose relationship is a key element" "as to toxic tort reliability." *Parker v. Brush Wellman, Inc.*, Nos. 1:04-CV-606-RWS, 1:08-CV-2725-RWS, 2010 U.S. Dist. LEXIS 97702, at *16-17 (N.D. Ga. Sept. 17, 2010) (internal quotation marks and citation omitted); *see also, e.g.*, *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679 (6th Cir. 2011) ("[I]t is well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff's symptoms."); *Downs v. Perstorp Components, Inc.*, 26 F. App'x 472, 475-76 (6th Cir. 2002) ("Another significant flaw in [the expert's] method was the fact that he made no attempt . . . to identify independently what dose of [the toxin] is necessary to cause the conditions that he observed in [the plaintiff].").

Here, Dr. Tischkau's opinion that "[e]levated levels of estrogen are known to increase the risk of VTE" is missing this "key element." She has no opinion on what a safe or unsafe level of

Cmax, or highest concentration, for estrogen is. As she put it: "I don't think that can be known. I don't think that is known."[16] (Tischkau Depo. 368.) Similarly, Dr. Tischkau opines that the longer Tmax for ENG, as compared to the Tmax for EE, "leaves a significant time frame where estrogen may be unopposed by progestin, which could contribute to the development of VTE in certain women." (Tischkau Report at 22.) But again, she has "no opinion about … what levels of progestin are required to counterbalance the effects of estrogen." (Tischkau Depo. 379.) At her deposition, she plainly stated: "We don't know anything about how much progestin is needed to do that." (*Id.* 383, 389.)[17] Dr. Tischkau also concludes that the level of sex hormone binding globulin ("SHBG"), purportedly "a marker of relative estogenicity, and thus VTE risk," is higher with NuvaRing® use than with LNG-containing oral contraceptive use. Once again, however, Dr. Tischkau admits to not knowing what a safe or unsafe level of SHBG is or if such levels have been established. (*Id.* 307-08.)

Without knowledge of these foundational data points, Dr. Tischkau's opinions about NuvaRing®'s ability to cause an increased risk of VTE amount to mere guesswork and pure conjecture. For this reason too, they must be excluded from trial.

CONCLUSION

"Triers of fact often give great weight to the testimony of expert witnesses in part because [they] assume not only that [the experts] have great knowledge in their area of expertise, but also that they by virtue of their formal scientific training they [sic] are meticulous and disciplined in their methodology." *Abdishi*, 1999 U.S. Dist. LEXIS 14903, at *16-17.

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[16] In fact, when questioned about Clinical Trial 34237, which compared the blood serum levels of EE in users of NuvaRing® compared to the levels in users of a second-generation pill and the Ortho-Evra patch, Dr. Tischkau admitted that NuvaRing® users had the ***lowest*** EE levels of the three groups. (Tischkau Depo. 452-54.)

[17] Indeed, she has "no idea" whether the concept of balance between estrogen and progestin is a generally accepted method for assessing the safety of a hormone contraceptive. (Tischkau Depo. 387.)

Dr. Tischkau's use of words and ideas from sources she did not credit, reliance on studies she did not read, discussion of concepts she did not understand, and pronouncement of opinions that lacked support all demonstrate that her testimony falls far short of this standard.

For all of these reasons, Dr. Tischkau should be barred from testifying at trial.

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/s/ Melissa A. Geist
Melissa A. Geist
REED SMITH LLP
Princeton Forrestal Village
136 Main Street, Suite 250
Princeton, NJ 08540
(609) 987-0050

Thomas J. Yoo
REED SMITH LLP
355 S. Grand Avenue
Suite 2900
Los Angeles, CA 90071
(213) 457-8000

Dan H. Ball
Stephen G. Strauss
BRYAN CAVE LLP
One Metropolitan Square
211 North Broadway, Suite 3600
St. Louis, Missouri 63102-2750
(314) 259-2000

Attorneys for Organon USA Inc., Organon Pharmaceuticals USA Inc. LLC (f/k/a Organon Pharmaceuticals USA Inc.) Organon International Inc. and Merck & Co., Inc. (f/k/a Schering-Plough Corporation)